AUG - 4 2003

K031435
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510(k) SUMMARY—BoneSource® BVF

Submitter Name:	Howmedica Osteonics Corp.
Submitter Address:	59 Route 17 Allendale, New Jersey 07401
Contact Person:	Jennifer A. Daudelin, Regulatory Affairs Specialist
Phone Number: Fax Number:	201-831-5379 201-831-6038
Date Prepared:	April 23, 2003
Device Trade Name:	BoneSource® BVF
Device Common Name:	Hydroxyapatite Bone Void Filler
Classification Name and Number:	Filler, Calcium Sulfate Preformed Pellets 87 MQV
Predicate Device:	The BoneSource® BVF is substantially equivalent to the Stryker Instruments (Leibinger) BoneSource® HAC (K021440) and Synthes (USA) Norian® SRS® Bone Void Filler (K011897).
Device Description:	BoneSource® BVF is an injectable, self-setting, calcium phosphate cement that is biocompatible and bioresorbable.
Intended Use:	The BoneSource® BVF is intended only for bony voids or defects that are not intrinsic to the stability of the bony structure. The BoneSource® BVF is intended to be placed or injected into bony voids or gaps of the skeletal system (i.e. extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.
Conclusion:	This device, with respect to materials, device characteristics and intended use, is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2003

Ms. Debra Bing
Manager, Regulatory Affairs
Howmedica Osteonics Corporation
59 Route17
Allendale, New Jersey 07401-1677

Re: K031435
Trade/Device Name: BoneSource® BVF
Regulatory Class: Unclassified
Product Code: MQV
Dated: May 5, 2003
Received: May 6, 2003

Dear Ms. Bing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

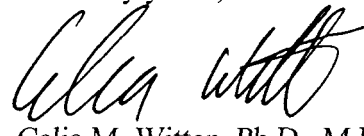
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031435

Device Name: **BoneSource® BVF**

Indications for Use:

The BoneSource® BVF is intended only for bony voids or defects that are not intrinsic to the stability of the bony structure. The BoneSource® BVF is intended to be placed or injected into bony voids or gaps of the skeletal system (i.e. extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031435

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)	X	OR	Over-The-Counter Use		

(Optional Format 1-2-96)